AUDIT REPORT FOR BELGIUM
MAY 16 THROUGH MAY 26, 2000

INTRODUCTION

PROTOCOL

- **Residue Program Audits** entailed audits by FSIS residue specialists of the National Residue Program and residue testing records in the meat inspection headquarters of the ~~National Veterinary Institute.~~

Institute for Veterinary Inspection.

- **Laboratory Program Audits** involved a laboratory audit by FSIS chemists and Quality Control Specialists. This included visits ~~*to two* laboratories~~, one performing analytical testing of field samples for the national residue testing program, and the other National Reference Laboratory.

Three laboratories were visited : the National Reference laboratory, the University of Gent laboratory, the Ministry of Agriculture laboratory.

SUMMARY OF FINDINGS

Inspection Program Audits

Effective controls were in place at five establishments and they were judged *Acceptable* (06, 45, 135,156, 477). Two establishments (93 and 93-1) were judged to be *Unacceptable* and one establishment (B-75) was judged *Acceptable Subject to Re-review* on the next audit. Establishment B-75 corrected its deficiencies in the dry storage area, however, other variations were observed during the current audit and they are mentioned later in this report. The two *Unacceptable* establishments were immediately delisted by Belgian authorities. Details of audit findings and observations, including compliance with HACCP, SSOP's, and testing programs for *Salmonella* and generic *E. coli* are discussed later in this report.

In mutual agreement between both veterinary services, the unacceptable plant was delisted. Written confirmation was given at the exit meeting. Since the audit, the delisted establishment has made all the necessary corrective actions. The plant was therefore again certified USDA/FSIS. It was agreed to review the other plant prior to the following annual certification.

In the case of bovine, each individual animal is identified within a week of birth with two plastic eartags with the same number (lifelong) and is issued a "passport" which must accompany the animal during transport. Swine are identified before the age of weaning with one plastic eartag with the landcode, a code (stockfarm or federation) and a serial number and for transport as a group using a shortenend farm code.

- **Sample Selection, Identification and Security.** The sample request control plan is generated centrally and provided to inspectors in the field ~~monthly~~. Inspectors make unannounced visits to the farm, collecting blood, urine and feces samples from 6 cattle or10 swine. A different team of inspectors from DG IV collects samples of feed from bulk bins and feed troughs. All samples are sealed and transported with appropriate paperwork to the designated laboratory. These samples are usually delivered in person.

weekly

Slaughter Establishment Activities

Sample Selection, Identification, and Security.

The monitoring sample request control plan is generated centrally by IEV and is provided to the teams of inspectors that are responsible for collecting residue samples. The plans for Group A compounds (hormone and prohibited substances) are generated monthly, while the remainder of the plan is generated on a weekly basis. There are six teams of inspectors distributed in each of the six districts (2 teams in the Flanders region and 4 in the French region.)(1). Sample selections are at discretion of the residue collection team and ~~are collected at random,~~(2) then placed in plastic containers and tamper-evident sealed. Each set of samples is identified with a pre-printed tag following established procedures. Samples are stored in containers with dry ice and are delivered to the designated laboratory, usually by the inspection team. Otherwise, taxis services are utilized.

(1) 4 teams in the Flanders region and 2 in the French region.
(2) and are targeted especially for group A substances.

- *H-Statute*

- When a violation occurs for an illegal or prohibited substance (Group A), the H-status is applied (for hormones),

By suspected sampling at the farm ten percent of animals are sampled and if one is found to be positive, all animals are sampled. Each animal testing positive is subsequently destroyed. In addition, the passports are modified to reflect the H-statute.

When a violation at the farm or at the slaughter establishment occurs for an illegal or prohibited substance (Group A), the H-status is applied, which triggers the additional sampling of 10 % of the animals at the slaughter establishment for 52 weeks. This intensified sampling is at the expense of the producer.
When a new violation for an illegal or prohibited substance is found within this period, the period is extended with 104 weeks.

- **State Police.** As part of the ~~CIR~~, the State Police provide enhanced controls and logistical support to investigations that follow all H-statute violations.

Multidisciplinary Division Hormones

- The State Police lead efforts to repress and prevent abuse of prohibited substances, which are sustained by weekly meetings between the Ministries. This weekly direct communication facilitates discussion of new and current files on active investigations of violations, and enables a unified plan for controls on farms and at slaughter establishments.~~This exchange is further enhanced by a link between the databases~~. The overall strategy, along with improvements evidenced by judicial actions taken against violators (farmers, distributors, illegal laboratories producing the mixtures, and pharmaceutical companies providing the base materials) are reported annually, evidencing a coordinated approach against the use of hormones.

There is no link between the databases but an exchange of information between the different services.

Findings and Recommendations

- *Residue Plan Design*

- There is no apparent systematic approach, rationale, or criteria for selecting veterinary drugs or other compounds to be included in the national residue control program. The decision to leave compounds in the program indefinitely limits the ability of Belgium to expand its program to include new drugs.

Although the above statement has to be considered in relation to the fact that directive 96/23/EC does not provide criteria for the inclusion of new veterinary drugs in residue control programs, the Belgian authorities appreciated very much this recommandation and will pay more attention to this issue.
In the design of the 2001 residue plan, corrective action is scheduled and will be realised within budgetary limits.

- The residue control program does not schedule residue testing of imported products (from third countries or member states), though random monitoring samples are collected on products imported into Belgium. Since imported product is currently used in product prepared and exported to the United States, there should be assurances that the product complies with U.S. tolerances.

Directive 89/662/EEC on intracommunity trade only allows at random sampling by Member States. The same applies to import from Third Countries who have in accordance with directive 96/23/EC a residue plan approved by the European Commission.
Only in the case of a positive result for an at random sample, targeted sampling may be applied.

LABORATORY PROGRAM AUDITS

- Findings

- The University of Gent laboratory was only accredited for qualitative analyses, though for those compounds with an MRL, the laboratory did have to make a judgement as to whether to send a sample to NRL for confirmation. That is, the laboratory primarily analyzed for prohibited compounds for which confirmation by mass spectrometry was required. They also analyzed for PCBs, with quantification (provided by internal standards) obtained concurrent with confirmation.

At the University of Gent laboratory, two units were visited at the same time :
-the laboratory for chemical analysis
-the laboratory for microbiological kidney testing (antimicrobials)

The Laboratory of Chemical Analysis is accredited for qualitative and quantitative analysis of clenbuterol in liver,and of PCBs in fatty tissue.
The other unit of the University of Gent laboratory is accredited for microbiological kidney testing (antimicrobials) and, in case of a positive result, has to appeal to NRL for qualification and quantification.

- None of the three laboratories had written guidelines (or SOP's) for qualifying a new analyst to demonstrate "readiness to perform." The informal procedures used are reasonable as described, but they should be written into SOP's.

Each laboratory has a SOP which describes the general procedure for qualifying new analysts. Every new analyst receives a specific training program which consist of several stages. Firstly the new analyst follows an experienced technician, followed by a practical training session under supervision. At the end of this training the new analyst must pass a qualification test. Qualification criteria are established and included in the SOP or the training program.

Each laboratory had a QC Coordinator. However, the Quality Assurance Coordinator was only available at the NRL. The University of Gent's coordinator worked part time, approximately two days a week. The NRL's Food Safety Section QA Coordinator was full time. The laboratories had a similar progression of procedures for reviewing data reports, i.e. analyst, program leader or senior analyst and finally the director of the unit. [The Director of the Food Safety Section, NRL managed over forty employees. With such a large unit, there may be a question as to depth of his review.].

Why is this sentence between brackets?

The raw data are first verified by a senior scientist and subsequently approved by the head of program and the head of section at the NRL.

The other two laboratories had smaller staffs. When a supervisor was not available, other staff were given signatory approval over final reports. With a limited number of staff, there were times in the University of Gent laboratory that only two levels of review were conducted. The QA Coordinators had no responsibility for data review. It may be advisable for both of these small groups and for a very large group to include the QA Coordinator in data review and approval when a manager is not available to perform this function, or is unable to review it in enough depth to detect mistakes. The QA Coordinator could, for instance, review a subset of reported data (choosing one or two samples from a set) to assure that quality criteria were meet.

At the University of Gent laboratory and the Ministry of Agriculture laboratory:

The levels of review conducted for official samples comprise of the person who construed the results, the head of the department who reviewed the results and finally the director of the lab. Since for each person a substitute is assigned there is a continuous follow-up for data review.
The QA coordinator has certainly a responsibility for data review during internal audits.

At the NRL

The QA coordinator of the NRL has a function of quality assurance and not a QC function. All the raw data are independently reviewed by the senior scientists.

Conclusions

The laboratory analysis portion of the Belgian residue control system appears to be run in a competent and quick-reacting manner. The three laboratories that were audited each had a number of small "defects" but none of them appear to be problematic. The major defect within the three laboratories appears to be the lack of an SOP for qualifying new analysts to perform on-going methods within the laboratory. The reporting systems appear to be quite effective and follow-up action on violations appears to be quite efficient.

Each laboratory has a SOP which describes the general procedure for qualifying new analysts. Every new analyst receives a specific training program which consist of several stages. Firstly the new analyst follows an experienced technician, followed by a practical training session under supervision. At the end of this training the new analyst must pass a qualification test. Qualification criteria are established and included in the SOP or the training program.

CONCLUSIONS

- The meat inspection system of Belgium was found to have effective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those which FSIS requires in domestic establishments. Eight establishments were audited; six were acceptable and two were unacceptable. The deficiencies encountered during the on-site establishment audits were adequately addressed. The unacceptable establishments were delisted by Belgian authorities. The Belgian residue laboratory and residue control programs were satisfactory.

Dr. Suresh P. Singh
Lead Auditor

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(Date)

The Belgian Inspection Services appreciated the remarks and recommandations of the U.S. audit team. Some minor language problems occured and can explain a few misunderstandings.
The remarks and recommandations of the US audit team will be taken into account within budgetary limits. Steps will be taken to meet these recommandations.

Appendix C

- **Audit of the National Reference Laboratory**

Laboratory: NRL (Scientific Institute of Public Health – Louis Pasteur)
Director: ~~Van der Groot~~

J.M. Degroodt

- The Food Safety Section's QA Coordinator reports to the Director of the Section. The Chief of NRL's QA Bureau apparently assessed his performed as a QA Coordinator. The amount of independence that the QA Coordinator has in resolving QA problems and reporting them to the NRL Director appeared to be limited, since he appeared to report to two individuals: the Director of the Food Safety Section and the Head of the QA Bureau. The laboratory was apparently cognizant of this apparent conflict since the Head of the QA Bureau did audit the Food Section and QA Coordinators from the other Sections or Departments would audit each other's organizations.

The escalation procedure in the quality manual foresees the possibility that the QA coordinator of the Food Safety Section reports directly to the director of the institute.

- The QA Coordinator was a certified auditor not only for BELTEST but also for GLP's. He had been applying some of the principles of GLP's to enhance the Food Safety Section's QA System, and was trying to have some input into data quality. Method SOP's contained validation information to insure QA input into method acceptance. (This suggestion was that the scientists sometimes had lower standards.) When the method validation SOP was initially developed, it specified a high and low standard for each set to determine whether the calibration curve had changed.

The analytical methods contain a summary of the method validation results. This improves the transparency of the analytical methods and facilitates the work of QA and of external assessors when reviewing the standard operating procedures.

- **Sulfonamides** [In contrast, FSIS is able to take action on approximately 16 sulfonamides.] Their recoveries are listed as greater than 55% for the method. [FSIS recoveries generally are 95 to 105%, using an internal standard.]

Why are those sentences between brackets?

Chloramphenicol. . One positive sample for chloramphenicol was confirmed using the ~~old~~ **(1)**(EC96/253) criteria. [That sample would not [That sample would not have been confirmed under the more stringent proposed standards.] **(2)**

(1) current

(2) Why is this sentence between brackets?

Appendix D

- **Audit of the University of Gent Laboratory**

Each standard, spike or stock solution was identified by a unique number for that type of solution and its preparation was described in an SOP. The date of preparation, pH, etc., were entered on a solution's label which was not retained as part of permanent records. There were no permanent entries to document the preparation of standards, spikes or stock solutions to identify who prepared a specific solution, when it was prepared, whether the pH needed to be adjusted, etc. Consequently, standard and spike solutions used for a specific analysis could not be not traced. The presumption was that the last solution prepared was the one used for an analysis. Whether such traceability is required by BELTEST's guidance is dependent upon interpretation of sections 5.3.3/6 and 7 and 5.4.1/1.

There is a permanent entree to document the preparation of standard solutions where the date and the analyst is indicated as well as the volumes of previous stock or working solutions used.
Corrective action is taken to mention pH control on the form.

- *Some solvents were labeled while others were not. The label did contain the date of receipt and each solvent had a unique identifying number. There were no records or notes that documented the manufacturer and lot of the solvents used in an analysis. Purchasing records were retained in the locked archives. Purchases were made whenever laboratory personnel noticed that the laboratory was running low on solvents.*

Corrective action is taken to record the lotnumbers. Traceability of the manufacturer can be found in the database with the number of the product used. The date of receipt can be traced through the delivery notes.

- The disks were retained in the laboratory for approximately a year. When asked to find the results for a specific sample, the analyst could not find it until she remembered that the sample was analyzed on an older instrument and the spectra was on another series of CDs. *Since it would have been difficult to find all of the documentation for a specific sample, the recommendation is made to develop an SOP which describes the manner in which information and records are retained. For instance, what information was entered in which notebook, where may information be found, etc.*

The information provided in the sample log notebooks is a logical description of the samples, the data-files, the identification number, remarks of the analyst. Since the instruments are used in the experimental phase of method development or for non official or research samples a procedure of retrieval of back-up information was created with approval of its logic by all analysts involved.
For that purpose 4 logbooks are created. This way of working facilitates the retrieval of data if asked for.

- The laboratory's focus was on analysis of prohibited substances and it is accredited for qualitative analyses of these substances. For those analytes with MRL's, the laboratory screened samples to determine which were to be sent to another laboratory to determine whether levels were above the MRL. The laboratory did not have criteria for this determination. It was left up to the analyst's judgement. *The recommendation is made to develop specific written criteria.*

At the University of Gent laboratory, two units were visited at the same time :
-the laboratory for chemical analysis
-the laboratory for microbiological kidney testing (antimicrobials)

The Laboratory of Chemical Analysis is accredited for qualitative and quantitative analysis of clenbuterol in liver,and of PCBs in fatty tissue.
Since the laboratory of chemical analysis is also accredited for the qualitative analysis of tranquillizers in animal tissue no quantification is performed. A semi-quantitative interpretation is based on the comparison of the area ratios of the sample with the spike at the MRL level for azaperone, azaperol, carazolol. If this value is within 75% of the MRL the sample will be sent to the NRL .

The other unit of the University of Gent laboratory is only accreditated for microbiological kidney testing (antimicrobials) and in case of positive result has to appeal to NRL for qualification and quantification.

- There does not appear to be a systematic approach or criteria for changing the focus (selecting new veterinary drugs or other substances) to be included in the residue control program. The decision to leave compounds in the program indefinitely limits the ability to expand the program to include new drugs, although there is a very active (research-based) program to develop methods for new substances thought to be used illegally in raising food producing animals.

Although there is in Belgium, an historical and systematic approach for illegal substances, there are within directive 96/23/EC no criteria for inclusion of new veterinary drugs in residue control programs. Belgium would like to be informed if such criteria are established by USDA/FSIS.

- As a result of the 1999 PCB/Dioxin crisis, the 2000 residue plan was expanded to include PCB and Dioxin testing. The Contaminants Surveillance Monitoring System (CONSUM) was developed to monitor feedstuffs for food-producing animals to provide trace back information and capability if a violation occurs. In addition, a new violation status (C-status) has been added, which will intensify sampling as a result of a contaminant violation.

PCB testing on products from animal origin was already performed before 1993, but due to the 1999 PCB-Dioxin contamination, the plan was expanded (CONSUM) and gained, by its statistical approach, largely in reliability to detect possible contamination.

The CONSUM testing program includes not only products from animal origin but also feedstuffs.
Maximum limits for PCB and dioxin contamination in foodstuffs and feedstuffs have been set. A violative result for PCB implicates a mandatory dioxin analysis.
Strict guidelines are established for preventing further contamination of the foodchain and for investigation of the entire farm to table concept, in order to detect the origin of contamination and organize recalls of contaminated products.

Separate from PCB testing, the CONSUM plan also includes sampling and analyses for dioxin in order to

- *It is recommended that such information be kept in the sample log notebook and in the archived sample files.*

All samples are checked for conformity upon receipt.If a non-conformity prevents the analyst from starting the extraction procedure the sampler is contacted and his instructions are followed. The non-conformity is recorded in the notebook or on the analysis sheet. This sheet is archived.

- Only one spiked sample and one tissue blank are analyzed with each batch of samples. For example, the analyst displayed a batch of 60 samples, analyzed over approximately two days (40+ hour run times), for which there was only one spiked sample. This level of quality control is well below appropriate standards. This is mitigated, in part, because of the inclusion of an internal standard in each analyzed sample. An unknown sample ("Q") sample is analyzed only once a month.

The spiked samples are analysed with each batch of samples at the same moment. This is to control the extraction procedure for each analyte. To control the extraction procedure of real samples an internal standard is added and checked if it meets the quality criteria prescribed in the analytical procedure. The performance and retention times of the detection system is checked with an injection of standard solutions.
If 60 samples are extracted in one day and injected over two days, injection of standard solutions in between samples is advisable but an extra spiked sample is not mandatory.

- A sample was found to be positive (sum of the 7 PCBs exceeded 200 ppb) for PCB's in animal ~~feed~~ (1)during the audit. The analyst is required to analyze quantitative recovery curves for the 7 PCBs monthly (minimum). A logbook (2)of the curves is not maintained. The curve is validated with each batch by analyzing a recovery standard (80 - 120 % recovery). Results for the positive sample were calculated using a standard curve (3)older than thirty days (in contradiction to the SOP) and the dates of standard curve analysis were not present on spreadsheet.

(1) The sample which was found positive had an animal origin : the detected PCBs were extracted from animal fat.

(2) Corrective action was taken by using a logbook since beginning of october, so that the curves and sequence list of the analyses can be checked easily. In any case, the sequence lists and curves could be checked by PC.

(3) At the beginning of each batch of samples two (a low and a high concentration) standard solutions are analysed and calculated using the standard curve to validate the instrument. The recovery of those standard solutions should be 90-110%. If so, the batch of samples can be run on the instrument, beginning with the spiked samples. Each batch of samples is ended with the analysis of the high concentration standard solution to validate the instrument again. The results of the routine samples and the spiked samples are calculated using the recovery curve (matrix).
Results for the positive sample were calculated using the recovery curve (matrix).
The fact that the recovery curve should not be older than one month , isn't mentioned in the SOP. It was decided by the people themselves to create a recovery curve every month, depending on the amount of samples.

- There were no calculations recorded in a book when standard solutions or reagents (pH buffers, 0.1000M NaOH.) were made. The laboratory staff started off with a "recipe" (an SOP), and ended with the final answer, but there were no calculations to see how they arrived at the final answer. Were there dilutions? Were some amounts "tweaked" to arrive at the answer? There was no traceability as to what balance or pH meter was used to measure the solutions.

Each balance is checked daily, the pH-meter is calibrated and checked daily.
Corrective action was taken and pH control will be mentioned on the chart provided for the preparation of solutions.

- New standards are not checked against the old ones. Doing this would allow analysts to check a new standard against an unexpired one and thereby verify results.

Standards are checked twice a year (old against new).

- The laboratory had a well-developed computer system. All the SOP's were listed and available on the computer. However, they could not find an SOP on writing SOP's. There was an extensive listing (table of contents) of SOP's but some revision numbers were not current. There were a few entries that had one or two revision numbers lower than those in the SOP. This shows the table of contents is not always updated when new SOP's are updated.

The list of SOP's was up to date. The SOP on writing an SOP is available in procedure 14.1.0

- The person who routinely performs a particular analysis approves the "Phase 4" results (the blind samples – unknown) obtained by a new analyst. The supervisor or equivalent should perform this. There doesn't appear to be a set number of samples required for qualifying a new analyst. There should be and there should be written SOP for this activity.

Corrective action was taken .
For an analyst to become "qualified" for an extraction procedure 6 batches of samples have to be extracted on different days ; as well as 10 series of samples have to be analysed and assessed for the interpretation of the raw data.

Appendix E

- **Visit to the Ministry of Agriculture Laboratory**

- For instance, records stated that a Gilson was used to clean up a sample, however, the laboratory owned three Gilsons and there was no reference as to which one was used for a particular analysis.

There are 3 identical Gilsons available for sample clean-up. Each Gilson system is labeled. When a system is used to clean up a set of samples (the set is identified by a serialnumber), the criteria specified for the Gilson system are checked prior to use. The serialnumber of the set of samples and the number of the Gilson used are listed on the worksheet. Therefore the Gilson system used for each set of samples can easily be traced back.

- Labeling of reagents and equipment was occasionally incomplete or missing. For example, several reagent bottles lacked labels and the laboratory had two Polaris GC's (one upstairs and one main level) that were not uniquely identified (other than by their location).

It isn't clear wich reagent bottles were not labeled. Most probably the solutions used were eluents for the LC-MS. Here indeed the bottles are identified by a label carrying a letter, referring to the (complex) composition as described in the SOP. Date of preparation, analyst,... are always mentioned. At the time of auditing only one of the two new Polaris GC-systems was in use. The installation of the second system was not yet complete. However a unique identification was present on the two systems: POL1 and POL2, like indicated in both logbooks.

- It appeared that analysts sometimes "checked" their own data without a higher level supervisor verifying the correctness of the data being reported out.

This is handled in Section 11 of the Quality Manual, subsection 11.3 "Checking results": A first checking of results is done by the person conducting the test. According to the speciality he checks whether the predefined criteria have been met.

A second checking is done by the head of department who verifies whether the tests have been conducted in a satisfactory way, whether there are no calculation or interpretation errors to be found and whether the check points have been observed.
A third checking is done by the head of the laboratory during electronical validation of the results or when signing the test reports.

detect background contamination in products from animal origin and feedstuffs.

- *Laboratory Program Audits*

- Three Belgian laboratories were reviewed during a three and a half-day period, with varying degrees of intensity. All three laboratories were accredited by BELTEST (Ministry of Economic Affairs) following EN-45001 for the methods they utilize. The methods for which they have been accredited varied. In concert with the philosophy of the EC, not only were muscle, kidney, liver and fat samples analyzed, but the laboratories often analyzed matrices such as urine, feces and feedstuffs. However, the laboratories do not appear to share the EC's analytical pursuit of prohibited substances below the EC's level of interest.

We don't understand the meaning of this last sentence. Could it be that here occured a misunderstanding on the "silent alert" strategy for prohibited substances?

- None of the three laboratories has written guidelines (or SOPs) for qualifying a new analyst to demonstrate "readiness to perform" for new analysts. The informal procedures, used as described, are reasonable but they should be written into the SOPs.

Each laboratory has a SOP which describes the general procedure for qualifying new analysts. Every new analyst receives a specific training program which consist of several stages. Firstly the new analyst follows an experienced technician, followed by a practical training session under supervision. At the end of this training the new analyst must pass a qualification test. Qualification criteria are established and included in the SOP or the training program.

All three laboratories used methods validated under current EU guidelines (93/256/EEC). None of the laboratories used methods validated under the proposed guidelines.

The draft Commission decision laying down performance criteria for analytical methods, is still under discussion within the services of European Commission

and between the European Commission and the Member States, and will only be applicable from January 1, 2003.

ENTRANCE MEETING

- On May 15, 2000, an entrance meeting with Belgian government officials was held at the Brussels offices of the Institute for Veterinary Inspection, Ministry of Public Health (IVK-IEV-MPH). This meeting was coordinated by Dr. Marc Cornelis, Director, ~~Animal Products~~ (MPH). Also attending were Dr. Jos Clysters, Director, Residue Investigation Group; Dr. L. Lengele, Director, Veterinary Services, Animal Health, Ministry of Agriculture (MOA); Dr. ~~Audle~~ Ermens; Dr. Guido Seurinck; Dr. Walter Smedts; Dr. Nelly Vermeeren ; and Dr. An Sevenants, Veterinary Staff Officers~~, MPH~~.

Dr. Marc Cornelis, Director, Veterinary Policy (MPH)

Dr André Ermens

Dr. An Sevenants,Veterinary Staff Officer Animal Health, Ministery of Agriculture.

- Government Oversight

- All inspection service veterinarians and inspectors in establishments certified by Belgium as eligible to export meat products to the United States were full-time Institute for Veterinary Inspection (IVK-~~IVE~~) employees of the Ministry of Public Health (MPH), receiving no remuneration from either industry or establishment.

(IVK-IEV)

INSPECTION PROGRAM AUDIT

- Testing for Generic *E. coli*

- *E. coli* and *Salmonella* testing is not required in Belgian slaughter establishments that are certified to export meat products to the United States. Animal and Plant Health Inspection Service (APHIS) regulations prohibit the importation of meat from hogs slaughtered in Belgium because of animal disease concerns. Belgium obtains meat for its products that are exported to the U.S. from hogs slaughtered in a third countries that are eligible for export to the United States.

Mandatory E. coli and Salmonella testing is required in Belgian slaughter establishments that are certified to export meat products to the United States.
There is a national monitoring program for Salmonella, Campylobacter, Listeria monocytogenes and E.Coli 0157 H7,as well as national hygiene monitoring based on E.Coli.

RESIDUE PROGRAM AUDITS

- Method and Scope

- The residue review subgroup was composed of three FSIS employees from the Office of Policy, Program Development and Evaluation, Office of Public Health and Science and Office of Field Operations. The subgroup met with Belgium officials from the Ministry of Public Health, Institute of Veterinary Inspection (IEV) and the Ministry ~~of Animal Health~~, General Administration for animal health and the quality of animal products (DGV),

of Agriculture (DG V is a department of the Ministry of Agriculture)

- *Interdepartmental Residue Cell (CIR)*

To be inserted:

The «Interdepartemental Residue Cell» is a policy unit which links the various services in a two monthly meeting.

The CIR has the following competences :

1 The coordination and centralization of all policy making activities of the different departments.

2 The evaluation of the control and inspection activities and the formulation of proposals for the improvement of legislation, procedures and guidelines.

3 The harmonization of the standing operating procedures of the different inspection services.

- Through the Central Bureau of Research in Brussels, ~~the Interdepartmental Residue Cell~~ (1) coordinates various investigations to trace back the use of illegal substances, gather intelligence and control active cases throughout Belgium. This enables unified action against residue violations, with special emphasis being placed on hormonal crime. Weekly meetings are held between five ministries: Agriculture Veterinary (DG IV and V), Public Health (IEV (2))Justice (Public Prosecutors), Finance (Customs) and Interior (State Police/National Hormone Cell).

(1)Multidisciplinary division hormones
(2)General pharmaceutical Inspectorate

- Legal Authority

- . These directives were transposed into Belgium law through the law of July 15, 1985, amended by the law March 17, 1997, the Royal Decrees of September 8, 1997 and October 11, 1997 and the Ministerial Decree of September 10, ~~1999~~

1997

- Residue Plan Design, Review and Approval

Correction of table 1

Table 1: Compounds added to the Belgium residue program since 1998				
GROUP	**COMPOUNDS**	**1998**	**1999**	**2000**
A3 Steroids	**Ethyl-Estrane-diol**	**X**	X	X
	16 OH Stanozolol	-	**X**	X
	Flugeston acetate	-	X	X
	Triamcinolone	-	**X**	X
	Methylpredniso lone	-	**X**	X
~~A4~~☼ Resorcyclic Acid Lactones	Estradiol benzoate	**X since 1989**	X	X
A5 β-agonists	Clenproperol	-	X	X
B2a Anthelmintics	Ivermectin	-	X	X
☼☼ **~~B2e~~** ☼☼☼ **~~NSAID~~**	Betamethasone	**X since 1994**	**X**	X
B3a Organochlorides	Dioxin	-	**X**	X

☼ Estradiol benzoate is an A3 substance
☼☼ B2f-other pharmacologically active substances
☼☼☼ Betamethasone is not a NSAID, but a corticosteroid and a prohibited substance in Belgium.

- In the case of prohibited substances, illegal drugs or mixture of drugs ("cocktails") that are seized by the police are submitted to the laboratories for identification. Once a method is developed(1) the compound is included in the plan. For example, the illegal use of 16 hydroxy (OH) stanozolol was confirmed through surveillance activities, ~~and this compound was added to the 2000 residue plan~~.(2)

(1) and after favorable opinion from the NRL

(2) and in july 1999, the compound was immediately added to the 1999 residue plan

- As an example, sampling of swine for tranquilizers (Group B2d) at slaughter was increased in 1999 and 2000 due to evidence that hogs were being sedated for transport. Reported 1999 results indicate that only 101 targeted samples were analyzed for swine in Group B2d (see Appendix C). This may be the result of production overestimation when developing the plan or perhaps a failure to collect samples that are scheduled. As another example, sampling of cattle, swine and poultry was increased at slaughter as a result of the dioxin crisis in 1999. It should be noted that in the case of PCBs, Belgium applies a statistical approach to sampling (300 samples per each species) in order to establish a confidence level for detection of the substance.

In addition 88 suspect samples from swine were taken and analysed for tranquillizers.
The planned higher frequency of targeted sampling for tranquillizers in swine could not be performed due to PCB-Dioxin crisis, which required a lot of personnel and means. But already at the beginning of 2000, attention was strongly focused on realizing the aims and goals (including repressive actions : R or H status)in this area.

- Residue Plan Operations
- *On-farm Activities*

- **Animal Identification.** The Belgium identification and registration system for farm animals (SANITEL) is the responsibility of the Ministry of Agriculture (DG V). Each farm (producer) is required to register and is responsible for identifying animals in accordance with requirements for the species. ~~In the case of bovine, each individual animal is identified within a week of birth and is issued a "passport" which must accompany the animal during transport. Swine are identified as a group using tattoos and transportation documents that identify the origin and destination of the group.~~